



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/701,253

11/04/2003

Pat D. O'Donnell

42581-P002P1

6108

61060

7590

09/08/2009

WINSTEAD PC
P.O. BOX 50784
DALLAS, TX 75201

EXAMINER

HOPKINS, CHRISTINE D

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

09/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/701,253	Applicant(s) O'DONNELL, PAT D.	
	Examiner CHRISTINE D. HOPKINS	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 9-17 and 20-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Appeal Brief filed 24 November 2008. Claims 1-21 are now pending. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Objections

2. Claims 3 and 4 are objected to because of the following informalities: at line 2, a comma should be inserted following "polymers". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3, 4, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3 and 4 at line 2 recites the limitation "filaments of the mesh section". There is insufficient antecedent basis for this limitation in the claims. Claim 18 at line 19 recites the limitation "the curved tip"; and at lines 23 and 26 recites the limitation "the distal end". There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 3, and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Staskin et al. (U.S. Pub. No. 2003/0045774). Staskin et al. (hereinafter Staskin) disclose surgical instruments and methods for introducing a sling into a patient suffering from urinary incontinence. Regarding claim 1, Staskin teaches a sling capable of being applied to an area beneath and supporting the urethra or bladder neck [0118]. A “tissue remodeling portion” is attached to and surrounding a section of the sling [0117]. The “tissue remodeling portion” is interpreted as the sheath of Staskin since its purpose, as that of the instant application, is to provide strength and structural reinforcement to the sling [0117]. The sling supporting the urethra may be composed of a surgical mesh [0026]. Referring to Fig. 4, a sling transfer instrument defines a curved shaft portion **60** between distal and proximal ends, with an attached insertion handle **64** at the proximal end and at the distal end, a dilator **54** for attaching the sling to the distal end of the shaft [0115].

With reference to claim 3, the polypropylene mesh, as taught by Staskin, contains filaments of woven material, each having a thickness of approximately .024 inches [0120].

With reference to claim 6, Staskin teaches that the shaft portion, or needle **60**, has a diameter of approximately 3.175 mm, or “approximately” 3.5 mm and less than 5.1 cm. Since the instant application provides no reason for a diameter of about 3.5 mm to about 4.0 mm, the dimensions of the needle as disclosed by Staskin are capable of transferring a sling to an implant site.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin in view of Inman et al. (U.S. Pub. No. 2003/0065246). Staskin discloses the invention as claimed, see rejection supra; however Staskin fails to disclose specific dimensions of the indentations on the transfer handle for accommodating the fingers of a surgeon. Inman et al. (hereinafter Inman) disclose an instrument for introducing a sling into the pelvic area of a patient suffering from urinary incontinence. Regarding claim 2, Inman teaches a handle **12** having a “digit control accommodation,” or channel

32 (see Figs. 2 and 3). The height of the handle is preferably between 3.25 in. to 4.75 in. [0046] whereby the width is preferably one-third of the height [0053]. Since the channel extends the width of the handle, the width of the “digit control accommodation” or channel **32** is approximately 1.08 in. to approximately 1.58 inches, thus falling within the range specified in claim 2. Furthermore, the length of the channel is approximately 1 in. [0051], and its depth is approximately one-half of the width [0053], thus the width, if it was 1.2 in, would bring the depth of the “digit control accommodation” to 0.6 in., or 1.5 cm in accordance with claim 2. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have fit a sling transfer instrument such as that disclosed by Staskin, to have the dimensions of the digit control accommodation as proposed by Inman, in an effort to provide a stable construction for a surgeon’s finger when inserting a sling within a patient during a surgical procedure.

Regarding claim 8, Staskin discloses the invention as claimed, see rejection supra; however Staskin fails to disclose a transfer shaft for a sling having a luminous coating. Inman teaches a rod **14** of a transfer instrument (see Fig. 3) having a reflective coating for aiding visibility for the surgeon [0058]. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have coated a transfer shaft, or needle, similar to that taught by Staskin, with a reflective or luminous material as suggested by Inman such that the instrument is easily viewed by the surgeon during application of a urinary incontinence sling within a patient.

9. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin et al. (U.S. Pub. No. 2003/0045774). Regarding claim 5, Staskin discloses the

dimensions of the sling, such dimensions being a length of 49-51 cm and a width of approximately 1.0 cm to 1.2 cm, thus capable of being approximately the widths specified at the central most position and opposite ends of the sling [0118]. However, Staskin does not disclose expressly that the mesh section is approximately 60 cm in length. Instead, Staskin indicates that the sling is approximately 49 to 51 cm in length and that the sheath covering the sling is approximately 52 to 58.5 cm in length [0118]. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use construct the mesh to be approximately 60 cm in length because Applicant has not disclosed that such a length provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Staskin's mesh and applicant's invention, to perform equally well with either the length taught by Staskin or the claimed approximate length because both would perform the same function of supporting the urethra and bladder neck ([0118] and [0119] of Staskin). Therefore, at the time of the invention it would have been prima facie obvious to modify Staskin to obtain the invention as specified in claim 5 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Staskin.

Regarding claim 7, Staskin discloses that the distal end of the shaft, or needle **60**, is oriented in a direction opposite of the curved portion (see Fig. 4). Furthermore, the distal end of the shaft portion is 1.0 cm, in length, since any length that is towards the distal end could be construed as "the distal end"; however Staskin does not disclose

Art Unit: 3735

expressly that the progressively curved shaft portion is approximately 4.0 mm in width. Instead, Staskin indicates that the width is approximately 3.175 mm in order to facilitate passage through various tissues and reduce tissue trauma in transvaginal deployment [0177]. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use construct the shaft portion to be approximately 4.0 mm in width because Applicant has not disclosed that such a length provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Staskin's shaft portion and applicant's invention, to perform equally well with either the width taught by Staskin or the claimed approximate 4.0 mm width because both would perform the same function of facilitating controlled passage during transvaginal deployment. Therefore, at the time of the invention it would have been prima facie obvious to modify Staskin to obtain the invention as specified in claim 7 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Staskin.

Allowable Subject Matter

10. Claims 4, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, see rejection supra, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and amended to be compliant with 35 U.S.C. 112, second paragraph. The following is a statement of reasons for the indication of allowable subject matter: regarding claim 4, the prior art of

record does not teach or fairly suggest a surgical instrument for treating incontinence as disclosed by Applicant, wherein a mesh section of a sling is comprised of absorbable polymers, and filaments of the section have a diameter of approximately .012 inch to 0.1 inch.

Regarding claims 18 and 19, the prior art of record does not teach or fairly suggest a suprapubic method for treating incontinence as claimed by Applicant, wherein the insertion handle of a first sling transfer instrument is used to guide a curved tip at the instruments distal end through the abdominal wall and retropubic space and further allowing the tip to be in contact with the posterior surface of the pubic bone as it traverses the retropubic space.

Response to Arguments

11. Applicant's arguments filed 24 November 2008 with respect to the rejection of claims 18 and 19 under 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive, however new grounds of rejection under 35 U.S.C. 112, second paragraph have been made in view of claims 3, 4, 18 and 19.

12. Applicant's arguments filed 24 November 2008 with respect to the rejection of claims 1, 3 and 6 under 35 U.S.C. 102(e) citing Staskin (U.S. Pub. No. 2003/0045774) have been fully considered and are not persuasive. Regarding claim 1, Applicant contends that Staskin does not teach "a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder. However, this argument

is not persuasive. Staskin teaches that the sling is of sufficient dimensions to support the urethra and bladder [0026] and [0116], and furthermore provides that the sling is of comparable dimensions of the instant application as indicated by its anticipation of claim 3, regarding the dimensions of the sling. According to its definition, "contoured" defines something which is molded or shaped to fit a particular contour or form. Even though the sling of Staskin is referred to as "tape" sling, it is held that the tape of Staskin is "shaped" to fit and support the urethra or bladder as noted in [0026] and [0116]. Furthermore, Staskin notes at [0118] and [0119] that alternative lengths, widths and thicknesses of the sling can also be used, including a wide variety of shapes, sizes, materials and treatments dependent upon the structure being supported, thus further providing that the sling of Staskin is also capable of being contoured to "the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder." Therefore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant further contends, regarding claim 1, that the radius of the curvature of the needle **60** of Staskin is substantially constant and hence it is not "progressively curved" as required by the claim. However, this argument is not persuasive. It is held that Fig. 4 shows a "progressively curved" needle, and paragraph [0115] describes the needle as curved and arc-shaped, which also are believed to anticipate a "progressively curved" needle.

Regarding claim 6, Applicant contends that Staskin does not teach that the needle **60** has a diameter of approximately 3.5 mm to 4.0 mm. However, this argument is not persuasive. Staskin discloses that the diameter of the needle is approximately 3.175 mm, and therefore the term anticipates claim 6 which incorporates an "approximate" diameter of 3.5 mm. Applicant further contends that the curvature of the needle of Staskin is not "progressively curved" but is rather substantially constant. However, this argument is not persuasive. The needle is believed to be "progressively curved" based on its curvature and arc-shape as displayed in Fig. 4. In view of the foregoing, the rejection of claims 1, 3, and 6 under 35 U.S.C. 102(e) citing Staskin (U.S. Pub. No. 2003/0045774) has been maintained.

13. Applicant's arguments filed 24 November 2008 with respect to the rejection of claims 5 and 7 under 35 U.S.C. 102(e) citing Staskin (U.S. Pub. No. 2003/0045774) have been fully considered but are moot in view of the new grounds of rejection under 35 U.S.C. 103(a) citing Staskin (U.S. Pub. No. 2003/0045774).

14. Applicant's arguments filed 24 November 2008 with respect to the rejection of claims 2 and 8 under 35 U.S.C. 103(a) citing Staskin (U.S. Pub. No. 2003/0045774) in view of Inman (U.S. Pub. No. 2003/0065246) have been fully considered and are not persuasive. Applicant contends that Inman does not teach a digit control accommodation on the insertion handle. However, this argument is not persuasive. The channel **32** is interpreted as the "digit control accommodation." The channel

Art Unit: 3735

provides a surface on the handle which may be used to control movement of the handle by the surgeon (Figs. 2-4). Applicant further contends that Staskin does not teach a digit control accommodation dimensioned approximately 2.5 to 4.5 cm in length, 1.0 to 4.0 cm in width and 1.5 cm in depth. However, this argument is not persuasive.

Staskin teaches a length of 2.54 cm, a width of 2.8 to 4 cm, and depth (being one-half the width) of 1.4 to 2 cm, thus covering the ranges presented in claim 2. In view of the foregoing, the rejection of claims 2 and 8 under 35 U.S.C. 103(a) citing Staskin (U.S. Pub. No. 2003/0045774) in view of Inman (U.S. Pub. No. 2003/0065246) has been maintained.

Terminal Disclaimer

15. The terminal disclaimer filed on 2 September 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,808,486 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/C. D. H./
Christine D Hopkins
Examiner
Art Unit 3735

